

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Healthcare Research and Quality****Patient Safety Organizations: Voluntary Relinquishment for the NCHA PSO**

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (PSO) an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” by the Secretary if it is found to no longer meet the requirements of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. AHRQ accepted a notification of proposed voluntary relinquishment from the NCHA PSO, PSO number P0025, of its status as a PSO, and has delisted the PSO accordingly.

DATES: The delisting was effective at 12:00 Midnight ET (2400) on April 30, 2023.

ADDRESSES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: <http://www.pso.ahrq.gov/listed>.

FOR FURTHER INFORMATION CONTACT: Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 06N100B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:**Background**

The Patient Safety Act, 42 U.S.C. 299b-21 to 299b-26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008 (73 FR 70732-70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for

the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from the NCHA PSO to voluntarily relinquish its status as a PSO. Accordingly, the NCHA PSO, PSO number P0025, was delisted effective at 12:00 Midnight ET (2400) on April 30, 2023.

NCHA PSO has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO’s possession.

More information on PSOs can be obtained through AHRQ’s PSO website at <http://www.pso.ahrq.gov>.

Dated: May 3, 2023.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Ryan White HIV/AIDS Program: Mpox Vaccine Distribution Request Forms, OMB No. 0915-xxxx-New**

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 10, 2023.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the acting HRSA Information Collection Clearance Officer, at 301-594-4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program: Mpox Vaccine Distribution Request Forms—OMB No. 0915-xxxx-New.

Abstract: On August 4, 2022, the mpox outbreak was declared a public health emergency (PHE) in the United States. From the outset, HRSA engaged with federal partners across HHS to provide resources to combat the spread of mpox; assist health care providers who are treating people who have mpox; and ensure those who are most at risk are the focus of vaccine response efforts.

HHS authorized HRSA to receive allotments of the JYNNEOS vaccine for mpox for rapid distribution to Ryan

White HIV/AIDS Program (RWHAP) recipients. HRSA was identified as a distribution partner due to the health care services provided to individuals with HIV and the number of uninsured and underinsured persons seen in RWHAP and Health Center Programs. The allotments were meant to supplement, not replace, vaccine efforts at jurisdictional levels.

To expedite dispensing the vaccine, HRSA provided the vaccine to dually funded RWHAP Part C and Health Center providers that care for at-risk populations. Most of the identified providers already had access to the Health Partner Ordering Portal (HPOP), a system HHS uses to quickly distribute the vaccines to clients. For providers who elected to receive the vaccine but did not have access to HPOP, HRSA registered them in the HPOP system. HRSA made 73 shipments to 57 (53 dually funded and four Part C only) RWHAP recipients who elected to receive and distribute the mpox vaccine.

RWHAP recipients that receive shipments of the JYNNEOS vaccine are required to upload administration and inventory/wastage data into HPOP on a weekly basis. The information collected includes federal or state PIN, contact, lot

number, description, number of vials, expiration date, courses/doses/bottles administered, bottles available, wastage, reason, and date reported.

RWHAP recipients who accept JYNNEOS vaccine from HRSA are also asked to submit data with information necessary for HRSA to assess the quantity of mpox vaccines requested and its distribution status. The information collected includes grant number; recipient name, point of contact, and phone number; shipping address; shipping point of contact, email address, and phone number; and number of boxes of mpox vaccine requested.

As a result of the PHE for mpox, the Assistant Secretary for Planning and Evaluation issued a Paperwork Reduction Act waiver for collection of these data. Since the PHE ended on January 31, 2023, HRSA is proposing to continue collecting these data until the end of 2025. This action will help to improve HRSA's ability to provide additional resources and assistance to RWHAP recipients, which may result in increased prevention of mpox among RWHAP clients.

Need and Proposed Use of the Information: HRSA will use the

information collected to (1) assess and improve its response to the mpox pandemic and (2) improve HRSA's ability to provide resources and assistance to RWHAP recipients in future public health emergencies.

Likely Respondents: Dually funded RWHAP Part C and Health Center recipients who accepted at least one shipment of mpox vaccine from HRSA.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Vaccine Distribution Report	57	1	57	0.5	28.5
Wastage Upload Report	57	1	57	23.4	1,333.8
Therapeutic Courses (Administered and Available)	57	1	57	10.4	592.8
Total	171	1,955.1

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases B Research Study Section.

Date: June 22-23, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mario Cerritelli, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892, 240-669-5199, cerritem@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,